

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 07 HOSPITALS

10.07.05 Residential Service Agencies

Authority: Health-General Article, Title 19, Subtitle 4A, Annotated Code of
Maryland

.01 Purpose.

The purpose of this chapter is to establish minimum standards for licensure of residential service agencies that conduct business in Maryland.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) “Activities of daily living” means normal daily activities including:

(a) Eating or being fed;

(b) Grooming, bathing, oral hygiene including brushing teeth, shaving, and combing hair;

(c) Mobility, transferring, ambulation, and access to the outdoors, when appropriate;

(d) Toileting; and

(e) Dressing in clean, weather-appropriate clothing.

(2) “Agency” means a residential service agency as defined in §B(25) of this regulation.

(3) “Branch office” means a satellite office of a residential service agency that:

(a) Is operated by the same person, corporation, or other business entity that manages the parent residential service agency; and

(b) Along with the parent residential service agency has the same:

(i) Ownership tax identification number as the parent residential service agency;

(ii) Upper-level management;

(iii) Policies and procedures; and

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(iv) Services within the same geographic area as the parent residential service agency.

(4) “Certified care” means a service or services that:

(a) May be performed for compensation only by an individual who is certified by the Board of Nursing, including a certified medication technician, a certified medicine aide, or a certified nursing assistant; and

(b) Include nursing functions that are routinely delegated by a registered nurse.

(5) “Certified medication technician” means an individual who:

(a) Has completed a Board-approved medication technician training program; and

(b) Is certified by the Board as a medication technician.

(6) “Certified medicine aide” means an individual who is:

(a) A certified nursing assistant who has completed a Board-approved course in medication administration; and

(b) Certified by the Board as a certified medicine aide.

(7) “Certified nursing assistant” means an individual, regardless of title, who:

(a) Routinely performs for compensation delegated nursing tasks which were delegated by a registered nurse or licensed practical nurse; and

(b) Is certified by the Maryland Board of Nursing as a certified nursing assistant.

(8) “Client representative” means an individual with legal authority to make decisions on behalf of the client as set forth in Regulation .13 of this chapter.

(9) “Clinical record” means a written account of all services provided to a client by the agency as well as all pertinent medical information necessary to provide care.

(10) “Department” means the Maryland Department of Health and Mental Hygiene.

(11) “Governing authority” means the individual, partnership, agency, group, corporation, or other entity that is designated to assume full responsibility for the policy determination, management, operation, and financial liability of the agency.

(12) “Home health care” includes any of the following services:

(a) Audiology and speech pathology;

(b) Dietary and nutritional services;

(c) Drug services;

(d) Home health aide;

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

- (e) Laboratory;
- (f) Medical social services;
- (g) Nursing;
- (h) Occupational therapy;
- (i) Physical therapy;
- (j) Provision of invasive medical equipment; and
- (k) Home medical equipment services.

(13) “Home medical equipment services” means the delivery, installation, maintenance, or replacement of, or instruction in the use of, medical equipment used by a sick or disabled individual to allow the individual to be maintained in a noninstitutional environment.

(14) “Household or family support services” means performance of tasks necessary to supplement an individual’s ability to perform:

- (a) Child care for children who require no medical attention; or
- (b) Instrumental activities of daily living.

(15) “Informal dispute resolution conference (IDR)” means an informal meeting that provides a licensee the opportunity to question the Department about deficiencies cited on a recent inspection.

(16) “Informed consent” means the willing, uncoerced acceptance of medical intervention by a client or a client representative with legal authority to make health care decisions after adequate disclosure of the nature of the intervention, and its risks and benefits, as well as alternatives with their risks and benefits.

(17) “Instrumental activities of daily living” means:

- (a) Light housekeeping and home management;
- (b) Meal planning and preparation; or
- (c) Shopping and errands.

(18) “Intravenous therapy” means the provision of services and monitoring and instruction related to substances that are administered intravenously, including but not limited to:

- (a) Total parenteral nutrition (TPN);
- (b) Hydration therapy;

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

- (c) Chemotherapy;
- (d) Antibiotic therapy; and
- (e) Blood and blood products.

(19) “Invasive medical equipment” means a device that invades tissue or a body cavity for the purpose of maintaining treatment modalities, including but not limited to:

- (a) Intravenous lines, whether enteral or parenteral;
- (b) Catheters;
- (c) Ventilators;
- (d) Gastric or nasogastric tubes;
- (e) Tracheostomy; and
- (f) Ostomies.

(20) “Law enforcement agencies” mean the Maryland State Police or a police agency of a county or municipal corporation.

(21) “License” means a document issued by the Secretary to a person to operate a residential service agency in this State.

(22) “Medical equipment” means technologically sophisticated medical devices including but not limited to:

- (a) Oxygen and oxygen delivery systems;
- (b) Ventilators;
- (c) Respiratory disease management devices;
- (d) Electronic and computer-driven wheelchairs and seating systems;
- (e) Apnea monitors;
- (f) Transcutaneous electrical nerve stimulator (T.E.N.S.) units;
- (g) Low air loss cutaneous pressure management devices;
- (h) Sequential compression devices;
- (i) Neonatal home phototherapy devices;
- (j) Feeding pumps; and
- (k) Electrically powered hospital beds.

(23) “Personal care provider under the Medical Assistance Personal Care Program” means an individual or personal care agency that has been approved by the Department as meeting requirements set forth in COMAR 10.09.20 and 10.09.36 to provide personal

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

care services to individuals who are certified for and receiving Medical Assistance benefits.

(24) “Plan of correction” means a written response from the residential service agency that addresses each deficiency cited as a result of an inspection by the Department.

(25) Residential Service Agency.

(a) “Residential service agency” means:

(i) An individual, partnership, firm, association, corporation, or other entity of any kind that is engaged in a nongovernmental business of employing or contracting with individuals to provide at least one home health care service for compensation to an unrelated sick or disabled individual in the residence of that individual; or

(ii) An agency that employs or contracts with individuals directly for hire as home health care providers.

(b) “Residential service agency” does not include:

(i) A home health agency that is licensed under Health-General Article, Title 19, Subtitle 4, Annotated Code of Maryland;

(ii) An individual, partnership, firm, association, corporation, or other entity of any kind that is required to be licensed as a home health agency under Health-General Article, Title 19, Subtitle 4, Annotated Code of Maryland;

(iii) A home-based hospice care program that is licensed under Health-General Article, Title 19, Subtitle 9, Annotated Code of Maryland;

(iv) A hospital that is licensed under Health-General Article, Title 19, Subtitle 3, Annotated Code of Maryland;

(v) A related institution that is licensed under Health-General Article, Title 19, Subtitle 3, Annotated Code of Maryland;

(vi) A nursing referral service agency that is licensed under Health-General Article, Title 19, Subtitle 4B, Annotated Code of Maryland, that screens or refers individuals for a client’s selection or rejection as its sole business operation, and does not itself provide any home health care service;

(vii) A personal care provider under the Medical Assistance Personal Care Program;

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(viii) An individual practicing in a health occupation for which the individual is authorized to practice under Health Occupations Article, Annotated Code of Maryland;

(ix) A business entity consisting of a group of individuals licensed under the same title of Health Occupations Article, Annotated Code of Maryland, which provides only that same, single, licensed health care service to its clients; or

(x) A residential rehabilitation services provider approved under regulations adopted under Health-General Article, §10-901, Annotated Code of Maryland.

(26) “Secretary” means the Secretary of Health and Mental Hygiene.

(27) Significant Change of Condition.

(a) “Significant change of condition” means a change in a client’s health, functional, or psychosocial condition that causes either an improvement or a deterioration in a client’s condition.

(b) “Significant change of condition” does not include any ordinary, day-to-day fluctuations in health status, function, or behavior or an acute short-term illness, such as a cold, unless these fluctuations continue to reoccur.

(28) “Skilled care” means a service or services that may be provided only by an individual who:

(a) Is licensed under Health Occupations Article, Annotated Code of Maryland; and

(b) Exercises specialized knowledge, judgment, and skill.

(29) “Skilled services” means services provided by or under the supervision of a registered nurse and in accordance with the plan of treatment.

(30) “Waiver of services” means an informed agreement by a competent adult client to receive certified care or skilled services that are less than the level of care that is recommended by the licensee or a representative of the licensee.

.03 License Required.

A. A person, partnership, corporation, association, or other entity may not conduct or operate an agency in this State without first obtaining a license from the Secretary and complying with the regulations of this chapter.

B. An agency that provides only household or family support services as defined in Regulation .02B(14) of this chapter does not require licensure.

C. Separate License Required.

(1) Except as provided in §C(2) of this regulation, a separate license is required for each agency.

(2) A branch office may operate under the same license of the agency.

D. Posting of a License. The licensee shall display the agency's current license in a conspicuous place, at or near the entrance of the agency's office.

E. This chapter does not preclude an agency from operating with independent contractors.

.04 Licensing Procedures.

A. Application for License.

(1) To obtain and maintain a license, an applicant shall meet all of the requirements of:

(a) This chapter; and

(b) Other applicable federal, State, and local laws and regulations.

(2) An applicant shall submit:

(a) An application on a form developed by the Department;

(b) Verification that the applicant or corporate representative is 21 years old or older;

(c) Documentation of any prior denial, suspension, or revocation of a license or certification to provide care to third parties;

(d) Identification of any individual or corporate owner of a 25 percent or more interest in the agency;

(e) A current criminal background check and documentation of any conviction of the applicant or person identified in §A(2)(d) of this regulation;

(f) Ownership information as specified on an addendum to the application;

(g) Information concerning any license or certification held by the applicant under Health Occupations Article or Health-General Article, Annotated Code of Maryland, including prior or current operation of a similar health care program by the applicant;

(h) Disclosure of any criminal charges or convictions, and disclosure of any findings of violation of:

(i) Medicare and Medicaid laws and regulations;

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(ii) Health-General Article, Annotated Code of Maryland; or

(iii) Health Occupations Article, Annotated Code of Maryland;

(i) Information demonstrating the financial or administrative ability to operate an agency in compliance with this chapter, which shall include at a minimum a business plan that contains a:

(i) 1-year operating budget;

(ii) Marketing plan that identifies the populations to be served; and

(iii) Detailed and specific description of agency services;

(j) Copies of the agency's policies and procedures as specified in Regulation .08B of this chapter;

(k) Proof of Workers' Compensation for all employees as required by the Maryland Workers' Compensation Commission; and

(l) A nonrefundable 1-year license fee of \$500 made payable to the Department.

B. Additional Requirements for Initial Licensure.

(1) If the applicant, owner, or person identified in §A(2)(d) of this regulation has had their license suspended or revoked by the Department that person may not own, operate, or manage another agency for 10 years without good cause shown. After 10 years, the applicant shall submit evidence to the Department that the applicant is capable of owning, managing, or operating an agency within the laws and regulations.

(2) If an applicant, owner, or person identified in §A(2)(d) of this regulation operates or manages an agency, that applicant, owner, or individual may not apply to open additional agencies, if the agency:

(a) Has had sanctions imposed within the last 2 years; and

(b) Has not achieved compliance with the regulations at the time of application for licensure.

(3) The Department reserves the right to deny licensure for a residential service agency to an applicant, an owner, or an individual identified in §A(2)(d) of this regulation, based on that person's prior:

(a) History of violations of residential service agency regulations; or

(b) Criminal history that the Department determines may be potentially harmful to clients.

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

C. The Department shall review all applications for licensure to determine whether the applicant:

(1) Can provide appropriate services to sick or disabled individuals who require care in the individuals' residence; and

(2) Meets the regulatory requirements of this chapter.

D. In addition to any other rights of inspection, before approving or denying an application for licensure, the Department may conduct an announced or unannounced on-site inspection of the agency.

E. Based on information provided to the Department by the applicant, the Secretary shall:

(1) Approve the application unconditionally;

(2) Approve the application conditionally, which may include, among other conditions, requiring:

(a) The applicant to use the services of a management firm approved by the Secretary; or

(b) A licensure term of less than 1 year; or

(3) Deny the application.

F. The Secretary may not require the use of a management firm for a period in excess of 24 months.

G. A person aggrieved by a decision of the Secretary under this regulation to deny a license application may appeal the Secretary's action by filing a request for a hearing consistent with Regulation .28 of this chapter.

H. Duration of License. A license is valid for 1 year from the date of issuance, unless:

(1) Surrendered, suspended, or revoked; or

(2) It is a provisional license as described in §J of this regulation.

I. License Renewal. A licensee shall submit to the Department:

(1) An application for license renewal;

(2) A nonrefundable 1-year license renewal fee of \$500 payable to the Department;

(3) Copies of any policies and procedures that have changed substantively since they were previously reviewed by the Department, including those relevant to:

(a) Handling of complaints made to the agency; and

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

- (b) Evaluation and assessment of clients;
- (4) Valid professional licenses and certificates for all current employees; and
- (5) An annual data collection survey in the form and manner prescribed by the Secretary with each application for license renewal.

J. Licenses for Less than 1 Year.

- (1) The Department may issue a provisional license if:
 - (a) The agency intends to provide services limited to skilled nursing and home health aid services; or
 - (b) The residential service agency is not in full compliance with this chapter, but, in the opinion of the Department, the:
 - (i) Noncompliance does not constitute a safety or health hazard; and
 - (ii) Applicant or licensee has submitted a plan of correction that is acceptable to the Department which satisfactorily addresses the correction of each deficiency within a timeframe acceptable to the Department.
- (2) A provisional license may not be extended beyond its expiration date.

K. If an agency fails to comply with the regulations of this chapter and the Department needs to conduct more than one on-site preclosure visit, the Department may:

- (1) Charge \$250 per additional on-site visit; or
- (2) Deny the license.

.05 Changes in an Agency That Affect the Operating License.

A. Change of Services or Name.

- (1) During the licensure period, a licensee may not:
 - (a) Provide services for which it has not been approved to provide; or
 - (b) Change the name under which the program is doing business without the Department's approval.
- (2) When the licensee wants to provide additional services which require a license under this chapter, before offering the services, the licensee shall submit to the Department:
 - (a) A new application and written request for a new license citing the additional services the agency wants to provide;

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(b) Policies and procedures pertaining to the additional services the agency wants to provide; and

(c) An application fee as required by Health-General Article, §19-4A-03(c), Annotated Code of Maryland.

(3) When there is a change in name or address of the licensee, but no change of ownership, an amended license is required and the licensee shall pay \$50 for the issuance of an amended license.

(4) Sale or Transfer of an Agency.

(a) If a sale or transfer of an agency causes a change in the person or persons who control or operate the agency, the agency is considered a new agency and the licensee shall apply for a new license and conform to all regulations applicable at the time of the transfer of operations.

(b) The transfer of any stock which results in a change of the person or persons who control the agency or the transfer of any stock in excess of 25 percent of the outstanding stock constitutes a sale.

B. Voluntary Closure or Change of Residential Service Agency Ownership.

(1) A licensee shall notify the Department in writing at least 45 days in advance of any intention to:

- (a) Voluntarily close;
- (b) Change ownership; or
- (c) Sell its agency.

(2) The licensee shall include the following information in the notice to the Department:

(a) The method for informing clients or client representatives, if applicable, of its intent to close, change ownership, or sell its agency; and

(b) The actions the licensee will take to assist clients in securing comparable services and assistance, if necessary.

(3) A licensee shall notify clients or client representatives, if applicable, of any proposed changes set forth in §B(1) of this regulation, in writing, at least 45 days before the effective date of the proposed change.

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(4) Whenever ownership of an agency is transferred from the person or organization named on the license to another person or organization, the future owner shall apply for a new license. The future owner shall file an application for a license at least 45 days before the transfer.

(5) The Department shall issue a new license to a new owner who meets the requirements for licensure under this chapter. The former licensee shall return its license to the Department by certified mail.

(6) A licensee named in the original license remains responsible for the operation of the agency until a new license is issued to the new owner. The current licensee remains responsible for correction of all outstanding deficiencies and impending sanctions until a new license is issued to the new owner. After a new license is issued, the new owner shall become responsible for correction of all outstanding deficiencies and impending sanctions.

(7) In addition to the notice to the Department required by §B(1) and (2) of this regulation, after an agency closes, the licensee shall:

(a) Notify the Department of the date of closure; and

(b) Return all licenses, past and present, to the Department by certified mail.

C. Changes to Licensure Information. A licensee shall immediately notify the Department of any change in the information the licensee had submitted with the most recent application.

D. License — Sale, Assignment, or Transfer. The license is valid in the name of the licensee to whom it is issued, and is not subject to sale, assignment, or other transfer.

E. If an agency fails to comply with §§A—D of this regulation, the Department may impose a fine of up to \$500 for each violation..

F. A license is void if the agency ceases to operate.

.06 Public Representation.

A. An agency shall include the following information in all of the agency's advertising and marketing materials:

(1) The agency's license number; and

(2) The statement "Licensed as a residential service agency by the Maryland Department of Health and Mental Hygiene, Office of Health Care Quality".

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

B. Misleading or False Advertising.

(1) A person may not advertise, represent, or imply to the public that an agency is authorized to provide a service that the agency is not licensed, certified, or otherwise authorized by the Department to provide under this chapter.

(2) A person may not advertise an agency in a misleading or fraudulent manner.

(3) A person licensed as an agency may not advertise that it is licensed as a hospice, home health agency, or nursing referral service agency unless it is separately licensed with the Department as such.

C. A person who violates this regulation is subject to referral for criminal prosecution and imposition of civil money penalties in accordance with Regulations .21—.23 of this chapter.

.07 Inspection by the Department.

A. Residential Service Agency to be Open for Inspection.

(1) The Department or its designee may conduct announced or unannounced licensure inspections or complaint investigations to ensure compliance with the requirements of this chapter.

(2) The agency shall be open for inspection by the Department during all hours identified in the agency's application as routine business hours.

B. Access to Agency and Sites Where Services Are Offered. Upon the request of the Department, an agency shall:

(1) Make its offices available for inspection during other than its routine business hours;

(2) Assist the Department in gaining access to sites where services are provided for the purpose of conducting inspections to:

(a) Ensure that the agency is in compliance with the regulations of this chapter;
and

(b) Enable the Department to investigate and resolve complaints filed against the agency.

C. Records and Reports.

(1) Inspection.

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(a) A licensee shall maintain records and reports to support compliance with the regulations of this chapter. All records and reports shall be open to inspection by the Department.

(b) Except for the records permitted to be stored off site, a licensee or licensee's designee shall immediately, upon request, provide copies of records and reports, including medical records of clients, to the Department. The Department shall, if requested, reimburse the licensee for the cost of copying records and reports.

(2) Maintenance.

(a) The residential service agency shall maintain files on site pertaining to:

- (i) Current clients;
- (ii) Clients that have been discharged within the last 12 months;
- (iii) Current staff;
- (iv) Staff that have been discharged within the last year; and
- (v) Quality assurance activities.

(b) All other records may be stored off site, but shall be available for inspection within 24 hours of the Department's request.

D. An agency shall make available upon request to clients, client representatives, potential clients, or federal, State, or local regulatory or law enforcement agencies any statements of deficiencies, reports, and plans of corrections.

E. Notice of Violations.

(1) If a complaint investigation or survey inspection identifies a regulatory violation, the Secretary shall issue a notice:

- (a) Citing the violation or deficiency;
- (b) Requiring the residential service agency to submit an acceptable plan of correction within 10 calendar days of receipt of the notice of violation or deficiency;
- (c) Advising the residential service agency that failure to correct cited violations or deficiencies may result in sanctions; and
- (d) Offering the residential service agency the opportunity for an informal dispute resolution conference (IDR).

(2) The plan of correction referred to in §E(1)(b) of this regulation shall include the date by which the licensee shall complete the correction of each deficiency. Failure to

return an acceptable plan of correction within the allotted timeframe may result in a sanction.

(3) When a licensee requests an IDR as provided in §F of this regulation, the licensee shall file a plan of correction within the required time, except to the extent that the licensee contests specific findings. If the licensee contests specific findings, absent the Department's directive, a licensee may delay submitting its plan of correction with respect to those specific findings until 5 days after the licensee is provided oral or written notice of the outcome of the IDR.

F. Informal Dispute Resolution (IDR).

(1) A licensee may request an informal dispute resolution conference (IDR) to question violations or deficiencies within 10 days of receiving the statement of deficiencies. The written request for an IDR shall fully describe the disagreement with the statement of deficiencies and be accompanied by any supporting documentation.

(2) At the discretion of the Office of Health Care Quality, the IDR may be held in person, by telephone, or in writing. In-person IDRs are informal in nature and are not attended by counsel.

(3) The IDR process may not delay the effective date of any enforcement action.

.08 Administration.

A. Governing Authority.

(1) The agency shall have a governing authority.

(2) The governing authority shall:

(a) Convene at least annually with management staff to review and advise the agency on policies; and

(b) Keep minutes, including:

(i) The participants of any meeting;

(ii) Agenda items considered; and

(iii) Actions taken.

B. Policies and Procedures.

(1) An agency shall develop and implement policies and procedures, including but not limited to:

(a) Administration, including:

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

- (i) Scope of services;
- (ii) Delineation of services provided by the agency when the agency coordinates care within the agency or with another provider;
- (iii) Notification to the client or client representative with legal authority to make health care decisions of the agency's responsibilities to coordinate care when appropriate;
- (iv) Admission criteria;
- (v) Assessment of potential clients before their acceptance into the program;
- (vi) Billing and service records, maintenance of charges, and similar items, except for those clients receiving services through a managed-care health benefits plan or third party payor, in which case records are maintained as required by the third party payor;
- (vii) Quality assurance program; and
- (viii) Clinical management, including assessment, plans, delegation, and supervision;
- (b) Personnel, including:
 - (i) Job descriptions and educational qualifications for all employees and contractors;
 - (ii) Skill assessments of all employees and contractors; and
 - (iii) Health requirements for employees and contractors;
- (c) Patient care, including:
 - (i) Provision of home health care services and criteria for determining the need for skilled services;
 - (ii) Administration of drugs;
 - (iii) Enteral and parenteral nutrition procedures;
 - (iv) Frequency of client monitoring; and
 - (v) Training and retraining of clients or their family members, when indicated;
- (d) Informed consent when:
 - (i) A client or client representative with legal authority to make legal decisions, signs an informed consent form consenting to changes to the agency's recommended plan of care; or

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(ii) A client signs an informed consent form consenting to assistance by a nonlicensed individual with treatments of a routine nature, or with the self-administration of medications; and

(e) Environment and safety, including:

(i) Preparation and storage of enteral formulas, intravenous therapies, other supplies, equipment, and similar items;

(ii) Infection control procedures;

(iii) Disposal of biomedical waste;

(iv) Maintenance of equipment; and

(v) Emergency procedures.

(2) The Department may waive the requirement of a policy and procedure that is required in §B of this regulation upon the agency's written explanation as to why the policy and procedure is inappropriate or unnecessary to the agency's specific operation.

(3) An agency that provides invasive equipment or supplies, such as intravenous therapy, shall arrange for 24-hour-a-day equipment maintenance service in case of equipment failure.

.09 Complaint Process.

A. Internal Complaint Process. An agency shall institute an internal client complaint process that includes:

(1) Notice to the client or the client representative of the complaint process;

(2) Protocols to investigate complaints; and

(3) A mechanism for the receipt and timely investigation of written complaints that ensures that the client's services will not be disrupted due to the filing of a complaint.

B. Internal Complaint Investigations.

(1) All investigation reports shall include:

(a) Time, date, place, and individuals involved;

(b) Complete description of the complaint;

(c) Disposition of the complaint; and

(d) Follow-up activities and steps taken to prevent its reoccurrence.

(2) If the agency does not conduct a complaint investigation, the agency shall document in the complaint record the reason for not conducting an investigation.

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(3) An agency shall provide notice to the following persons regarding the disposition of a complaint:

- (a) Client, or if the client is incompetent, the client representative;
- (b) Client's physician, if needed; and
- (c) Licensing or law enforcement agencies, when required by law.

(4) An agency shall maintain records to support its internal complaint investigation process.

C. An agency shall provide notice to clients of the Department's complaint hotline number for complaints about services provided by the agency or services that the agency failed to provide.

D. Availability of Internal Investigation Reports.

(1) The agency shall make investigation reports available to the Department immediately upon request.

(2) An agency shall provide a summary report of any complaint investigation for public inspection, upon request, to the extent permitted by law.

.10 Employee, Independent Contractor, and Contractual Employee Requirements.

A. An agency shall develop and implement policies and procedures to screen a prospective employee, independent contractor, or contractual employee who will provide services to clients.

B. Screening.

(1) Screening shall include:

(a) A State criminal history records check or a private agency background check as required under Health-General Article, Title 19, Subtitle 19, Annotated Code of Maryland;

(b) Verification of current professional licensure or certification under Health Occupations Article, Annotated Code of Maryland;

(c) A basic health screening, including tuberculosis screening;

(d) Verification of references;

(e) Verification of employment history;

(f) Completion of I-9 forms for employment;

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(g) Verification of identity and employment eligibility of an employee, independent contractor, or contractual employee;

(h) An in-person interview of an employee, independent contractor, or contractual employee before the individual is referred to clients; and

(i) Completion of a skills assessment and demonstration before client referral.

(2) An agency shall retain records of training in the personnel file.

C. An agency shall maintain records of information described in §B of this regulation for each employee, independent contractor, or contractual employee and retain the information in the agency's business office.

D. An agency may not knowingly provide or refer a caregiver who is not certified to provide services to a client unless the client:

(1) Does not require the caregiver to provide assistance with activities of daily living;

(2) Only requires assistance with activities of daily living and in the judgment of the supervising nurse, there are no predictable adverse health consequences; or

(3) Signs a waiver of skilled services form as required under Regulation .12D of this chapter.

E. An agency shall provide or refer a certified caregiver to a client who requires:

(1) A certified caregiver to perform activities of daily living; or

(2) Administration of medication.

F. If an agency is aware of an action or inaction by an individual who is provided or referred by the agency that may be grounds for action under Health Occupations Article, §§8-316 and 8-6A-10, Annotated Code of Maryland, the agency shall report the action or condition to the Board of Nursing and the Office of Health Care Quality immediately when the action or condition is known by the agency.

G. A nursing administrator, a registered nurse, a licensed practical nurse, and a certified nursing assistant shall have immunity from liability as described in Courts and Judicial Proceedings Article, §5-709, Annotated Code of Maryland, for making a report to the Board of Nursing as required under §F of this regulation. Other persons are entitled to the immunity from liability as described in the Courts and Judicial Proceedings Article, §5-708, Annotated Code of Maryland, for making a report to the Board of Nursing as required under §F of this regulation.

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

H. Use of Subcontract Agencies. If an agency subcontracts with another licensed agency to provide services, the subcontracting agency shall:

- (1) Verify personnel information outlined in §B of this regulation; and
- (2) Submit evidence to the contracting agency that verification has occurred.

.11 Training.

A. An agency shall ensure that individuals that are referred are trained appropriately to provide care that is needed by the agency's clients.

B. Sources other than the agency may provide training, as approved in writing by the Office of Health Care Quality.

C. At a minimum, training for individuals providing care in clients' homes shall include:

- (1) Instruction and supervised practice in relevant personal care services of the sick or disabled at home;
- (2) Identification of situations that require referral to a registered nurse, including significant changes in a client's condition;
- (3) Record keeping;
- (4) Ethical behavior and confidentiality of information;
- (5) CPR;
- (6) Standard precautions for infection control; and
- (7) Prevention of abuse and neglect.

.12 Services Provided.

A. An agency shall take reasonable measures to ensure that all individuals who are referred to provide services to clients do so in accordance with Maryland laws and regulations, including but not limited to the Health Occupations Article, Annotated Code of Maryland.

B. Provision of Services.

(1) A registered nurse shall assess each new client who requires skilled services and assistance with the activities of daily living.

(2) The registered nurse shall also:

(a) Participate in developing the client's plan of care and in assigning appropriate personnel;

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(b) Determine whether the client requires the services of a certified nursing assistant, or whether services may be provided by an individual who is not certified; and

(c) Participate in training and retraining the individuals who will provide the care, when indicated.

C. Plan of Care.

(1) A client's plan of care shall be based on assessments of the client's health, function, and psychosocial condition.

(2) An assessment of a client shall be completed:

(a) When the client is requesting or requiring services regulated by this chapter;

(b) Before the client receives services from the agency unless:

(i) The client does not request skilled care or skilled services; and

(ii) There is no reason to believe that the client requires skilled care or skilled services, such as discharge instructions requiring skilled care;

(c) Within 48 hours of when the client begins services when the client requires, including but not limited to:

(i) Wound and catheter care;

(ii) Treatment of stage three or stage four skin ulcers;

(iii) Ventilator services;

(iv) Skilled monitoring, testing, and aggressive adjustment of medications and treatments where there is the presence of, or risk for, a fluctuating acute condition;

(v) Monitoring of a chronic medical condition that is not readily controllable through available medications and treatments;

(vi) Infusion therapy;

(vii) Specialized intravenous therapies or nutrition support;

(viii) Monitoring for being at high risk for health or safety complications which cannot be adequately managed; or

(ix) A different level of care after notification of a significant change of condition;

(d) At the request of the client or the client representative;

(e) At least annually; and

(f) Except in the following circumstances:

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

- (i) Weather-related emergencies;
- (ii) Natural disasters; or
- (iii) Federal, state, or local declaration of an emergency.

(3) When a registered nurse determines in the nurse's clinical judgment that the client does not require an assessment within 48 hours of a significant change of condition as provided in §C(2)(c) of this regulation, the registered nurse shall:

- (a) Document the determination in the client's record; and
- (b) Ensure that an assessment of the client is conducted within 7 calendar days.

(4) The agency shall ensure that the care plan developed for the client at a minimum addresses:

(a) The services to be provided to the client, which are based on the assessment of the client;

- (b) When and how often the services are to be provided;
- (c) How and by whom the services are to be provided;
- (d) Long-range and short-range goals for the client; and
- (e) Physical needs, including safety measures to protect against injury.

(5) Client care plans shall be reviewed by a registered nurse or another health care practitioner who is authorized to do so under Health Occupations Article, Annotated Code of Maryland, when appropriate.

D. Informed Consent.

(1) An adult client who is competent to make decisions or a client representative with legal authority to make health care decisions may consent to make changes to the agency's recommended plan of care.

(2) A cognitively capable adult client, but not a client representative with legal authority to make health care decisions, may waive the licensee's recommendation of certified care services to be provided in the adult client's home to assist with treatments of a routine nature, or with the self-administration of medications.

(3) A cognitively capable adult client may waive the licensee's recommended skilled care.

(4) Consents.

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(a) The consent given under §D(1)—(3) of this regulation may be granted only after a discussion of the risks and benefits with the client or, if appropriate, the client representative with legal authority to make health care decisions. This discussion shall be reflected in an informed consent form.

(b) The informed consent form shall be:

(i) Signed and dated by the client, or the client representative with legal authority over health care decisions; and

(ii) Documented in the client's records.

(c) A form confirming a waiver of skilled services shall be signed by a cognitively capable adult client and maintained in the client's record.

(5) Client medications shall be administered in accordance with §F of this regulation.

E. Nursing Supervision.

(1) For clients who require skilled services or assistance with the activities of daily living, an agency shall have a registered nurse to provide oversight for:

(a) Implementation of the care plan;

(b) Delegation;

(c) Supervision; and

(d) Training.

(2) The registered nurse shall provide periodic, on-site supervision of care at least every 90 days unless the licensee administers medications to the client, in which case supervision shall occur at least every 45 days.

(3) The agency shall maintain accurate documentation of the supervision that is provided by the registered nurse.

F. Medication Administration. If agency employees, independent contractors, or contractual employees administer medications, the agency shall:

(1) Provide for administration of drugs and treatments by licensed or certified staff consistent with Maryland law and the client's plan of care, unless the client has executed an informed consent form under §D of this regulation;

(2) Provide for drugs and treatments to be administered only as ordered by the physician; and

(3) Document in the client's clinical record:

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

- (a) Medications administered or taken;
- (b) Medication errors; and
- (c) Adverse drug reactions and corrective action.

G. On-Call Services. The agency shall:

- (1) Establish a procedure by which current clients or their representatives may contact a representative of the agency by communication device at any time, 24 hours a day and 7 days a week;
- (2) Recognize and respond to emergency inquiries in a manner that is consistent with medical and nursing standards;
- (3) Ensure that the inquiry is directed to an individual for response as required by medical and nursing standards;
- (4) Ensure that the individual responds to an inquiry not later than 1 hour after the inquiry is received by the agency or sooner as necessitated by medical standards;
- (5) Maintain a log of inquiries that includes the identity of the response personnel, content of the inquiry, and the time of each inquiry; and
- (6) Provide clients or the client representatives with written procedures and the phone number for on-call service.

.13 Client Representative.

A. An agency shall recognize the authority of:

- (1) A guardian of the person under Estates and Trusts Article, §13-705, Annotated Code of Maryland;
- (2) A guardian of the property under Estates and Trusts Article, §13-201, Annotated Code of Maryland;
- (3) An advanced directive that meets the requirements of Health-General Article, §5-602, Annotated Code of Maryland;
- (4) A surrogate decision maker with the authority under Health-General Article, §5-605, Annotated Code of Maryland;
- (5) A power of attorney that meets the requirements of Estates and Trusts Article, Title 17, Annotated Code of Maryland;
- (6) A representative payee or other similar fiduciary; or

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(7) Any other person, if that person was designated by a client who was competent at the time of designation, and the client or client representative has provided the agency with documentation of the designation.

B. An agency may not recognize the authority of a client representative if the representative attempts to exceed the authority:

- (1) Stated in the instrument that grants the representative authority; or
- (2) Established by State law.

C. An agency shall:

(1) Document in the client's record the name of the person, if any, with the authority identified in §A of this regulation; or

- (2) Include the documentation creating the authority in the record.

.14 Clinical Records.

A. With the exception of §B of this regulation, an agency shall ensure that a clinical record is maintained for each client in a manner that ensures security and confidentiality, and includes at a minimum:

- (1) The documentation required by §D of this regulation;
- (2) Any currently effective health care orders;
- (3) Nurse's assessment
- (4) Rehabilitation plans, if appropriate;
- (5) The care plan;
- (6) Medications administered or taken, including:
 - (a) Dosage;
 - (b) Route of administration; and
 - (c) Frequency;
- (7) History of sensitivities or allergic reactions;
- (8) Nutritional requirements, including specific dietary plans;
- (9) Medically necessary supplies and equipment;
- (10) Care notes;
- (11) The name, address, and telephone number of:
 - (a) The client's physicians; and
 - (b) The client representative; and

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(12) The following documents for each client upon discharge:

(a) Directions for the safe continuation of care after discharge; and

(b) If skilled services have been provided, a discharge summary that includes the reason for discharge.

B. An agency that provides care to clients who are assessed as not requiring certified caregivers or skilled services shall maintain a client record, including but not limited to:

(1) Nursing assessment;

(2) Plan of care;

(3) Services provided;

(4) Any significant change of condition; and

(5) Any other pertinent information regarding the client being served.

C. An agency shall develop policies and procedures to ensure that all information relating to a client's condition or preferences, including any significant change of condition as defined in Regulation .02B(27) of this chapter, is documented in the client's record and communicated in a timely manner to:

(1) The client;

(2) The client representative, if appropriate; and

(3) All appropriate health care professionals and staff who are involved in the development and implementation of the client's care plan.

D. Care Notes.

(1) Appropriate staff shall write care notes for each client, at a minimum:

(a) On admission and at least weekly;

(b) Upon any significant changes in the client's condition; and

(c) When the care plan is modified.

(2) The agency shall ensure that all notes and reports that are entered in the clinical record, which may include an electronic record, are detailed, legible, chronological, dated, and signed with the name and title of the individual rendering the service.

E. The agency may accept orders for care with an electronic signature. Orders may be received by, but not limited to, mail, hand delivery, or facsimile transmission.

.15 Maintenance of Records.

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

A. The agency shall maintain a client's record for 5 years after the client is discharged. For a client younger than 18 years old, the agency shall maintain the client's record after discharge until the resident is 21 years old, or for 5 years after the record is made, whichever is later, except as otherwise provided in Health-General Article, §4-403, Annotated Code of Maryland.

B. If an agency ceases operation, the agency shall make arrangements to return the records to the client or client representative with legal authority to make health care decisions, or retain the records as required by §A of this regulation.

C. An agency shall:

- (1) Maintain the privacy and confidentiality of a client's medical records;
- (2) Release medical records or medical information about a client only with the written consent of the client or client representative, or as permitted by Health-General Article, Title 4, Subtitle 3, Annotated Code of Maryland; and
- (3) Maintain and dispose of a client's medical records in accordance with Health-General Article, Title 4, Subtitle 3 and 4, Annotated Code of Maryland.

D. In addition to the provisions of §§A—C of this regulation, the agency shall establish and implement procedures that ensure that:

- (1) Records of discharged clients are completed no later than 30 days after the date of discharge; and
- (2) Safeguards are in place to protect clinical record information against loss, destruction, or illegal or unauthorized use.

.16 Client's Rights and Responsibilities.

A. The agency shall ensure that agency staff develops and implements written policies and procedures concerning clients' rights and responsibilities.

B. The agency shall make the policies and procedures available to clients or client representatives.

C. The policies and procedures shall ensure that the agency provides the client or client representative with:

- (1) An estimate of costs associated with the services requested by the client;
- (2) A statement clarifying the costs that the client or client representative will be responsible for if services are not covered by third-party payors;

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

- (3) Fully itemized billing statements, including dates of services and unit charge, to be made available on request of the client or client representative;
- (4) The name of the caregiver or caregivers referred by the agency to provide the service or services;
- (5) The name and contact information for the individual who is responsible for supervising the client's care;
- (6) The telephone number where a client or the client representative can contact the agency 24 hours a day, 7 days a week regarding care; and
- (7) Disclosure of any subcontractual relationship with any individual or agency to be assigned or referred to provide care to the client.

D. Rights.

- (1) A client of an agency or, if appropriate, the client representative with legal authority to make health care decisions has the right to:
 - (a) Be treated with consideration, respect, and full recognition of the client's human dignity and individuality;
 - (b) Receive treatment, care, and services that are adequate, appropriate, and in compliance with relevant State, local, and federal laws and regulations;
 - (c) Participate in the development of the client's care plan and medical treatment;
 - (d) Refuse treatment after the possible consequences of refusing treatment have been fully explained;
 - (e) Privacy;
 - (f) Be free from mental, verbal, sexual, and physical abuse, neglect, involuntary seclusion, and exploitation; and
 - (g) Confidentiality.
- (2) A client or client representative has the right to:
 - (a) Make suggestions or complaints, or present grievances on behalf of the client to the agency, government agencies, or other persons without the threat or fear of retaliation;
 - (b) Receive a prompt response, through an established complaint or grievance procedure, to any complaints, suggestions, or grievances the participant may have; and

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(c) Have access to the procedures for making a complaint to the Office of Health Care Quality, and to:

(i) The Adult Protective Services Program of the local department of social services, if the client is an adult; or

(ii) The Child Protective Services Program of the local department of social services, if the client is a minor.

E. Advanced Directives. With the exception of durable medical equipment agencies, an agency shall:

(1) Provide information to a client about advance directives and the right to have an advance directive; and

(2) Obtain information regarding the client's advance directives to determine whether the advance directive information has an impact on care provided.

F. Client Directed Care. The agency shall honor the right of:

(1) A cognitively capable adult client, or a client representative with legal authority to make health care decisions, to refuse any portion of planned treatment or other portions of the treatment plan, except where medical contraindications to partial treatment exist; and

(2) A cognitively capable adult client to have an individual who is not certified to provide assistance with activities of daily living and treatments of a routine nature if the client signs a waiver of skilled services detailing the potential risks and benefits of waiver as required under Regulation .12D of this chapter.

G. Informed Consent. The agency shall provide sufficient information to the client or the client representative to allow the client or the client representative to make an informed decision regarding treatment as required under Regulation .12D of this chapter, including:

(1) The purpose and nature of an evaluation or treatment regimen;

(2) Alternatives to treatment;

(3) Side effects and benefits of a proposed treatment regimen and the alternatives to the treatment;

(4) The estimated cost of the treatment and the alternatives; and

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(5) The right to withdraw from treatment at any time, including the risks associated with withdrawing from treatment.

H. Client Participation. The agency shall allow a client, or client representative with legal authority to make health care decisions, to accept or reject, at the client's or client representative's discretion without fear of retaliation from the agency, any employee, independent contractor, or contractual employee that is referred by the agency.

.17 Special Requirements for the Provision of Intravenous or Related Therapies.

A. This regulation applies to intravenous or related therapy provided in the home.

B. A provider of intravenous or related therapies shall meet the requirements of this regulation in addition to meeting the requirements of Regulations .01 — .16 of this chapter.

C. Specialized intravenous therapies and nutritional support services administered enterally or parenterally shall be considered skilled nursing functions.

D. Medications.

(1) Medications and preparations used in the provision of intravenous or nutritional support shall be obtained from a licensed pharmacy.

(2) The agency shall document any adverse reactions associated with the therapy and notify the client's physician.

E. Education and Training. When an agency provides intravenous or related therapies, the agency shall provide:

(1) Education, training, and written instructions to the client, client representative, or the individual caring for the client before the initiation of treatment, which includes:

(a) Feeding formulation or medication preparation;

(b) Administration of the therapy;

(c) Accessing private care;

(d) Equipment maintenance;

(e) Recognition of complications of therapy, adverse medication reactions, and equipment malfunctions; and

(f) Mechanisms for accessing a clinician during business hours and at any time after hours for questions related to drug therapy, drug administration, or equipment troubleshooting or malfunctions; and

(2) Retraining and a review to the client, client representative, or the individual caring for the client as needed or requested.

F. The agency shall maintain a clinical record for a client receiving intravenous or related therapies, which, in addition to the documents required to be maintained in accordance with the provisions set forth in Regulations .14 and .15 of this chapter, includes the following:

- (1) Results of training or retraining of the client, client representative, or the individual caring for the client;
- (2) Composition, indication for use, role, and mode of administration of feeding formulas or medications; and
- (3) Summary statement at termination of the intravenous or related therapy which includes the results of therapy, complications, outcome, and disposition of the client.

.18 Special Requirements for the Provision of Ventilator Services.

A. A provider of ventilator services shall meet the requirements of this regulation in addition to meeting the requirements of Regulations .01—.16 of this chapter.

B. This regulation applies to ventilator services provided in the home, including:

- (1) Volume ventilation;
- (2) Pressure ventilation;
- (3) Emergency back-up power systems;
- (4) Alarms and troubleshooting equipment;
- (5) Emergency resuscitation; and
- (6) All related medical equipment used with the provision of ventilator services,

including but not limited to:

- (a) Nebulizers;
- (b) Suction equipment; and
- (c) Oxygen.

B. This regulation applies to ventilator services provided in the home, including:

C. Education and Training. When an agency provides ventilator services, the agency shall:

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(1) Use either a licensed registered nurse or a licensed respiratory care practitioner to supervise the provision of education and training and written instruction to the client, client representative, or individual caring for the client; and

(2) Provide retraining and review on a monthly basis, and as frequently as necessary.

D. Client Record. For a client receiving ventilator services, the agency shall maintain a clinical record, in addition to the documents required to be maintained in accordance with the provisions set forth in Regulations .14 and .15 of this chapter, that includes the following:

(1) An evaluation of use of the ventilator and all related medical equipment by the client, client representative, or individual caring for the client that includes:

(a) Training at least monthly on the provision of ventilator services; and

(b) Retraining, more frequently as needed, on the provision of ventilator services;

(2) A prescription that includes the mode, frequency, and ventilator settings;

(3) Respiratory and all specialized services, including the results, complications, and outcomes;

(4) Physician orders and pharmacy-dispensed respiratory medications;

(5) Evidence that the client, client representative, or individual caring for the client was instructed that medications are to be obtained from a licensed pharmacy; and

(6) A discharge summary when a client is no longer receiving ventilator-related services.

.19 Special Requirements for the Provision of Home Medical Equipment Services.

A. An agency that provides home medical equipment services shall meet the requirements of this regulation in addition to meeting the requirements of Regulations .01—.16 of this chapter.

B. Education and Training. When an agency provides home medical equipment services, the agency shall:

(1) Ensure that its personnel demonstrate competency in delivering and installing the equipment;

(2) Provide education, training, and written instructions to the client, the client representative, or the individual caring for the client on the use of the equipment at the time of installation; and

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(3) Provide the client, client representative, or the individual caring for the client the telephone number of the agency in the event of equipment failure or emergency.

C. Upon request, an agency shall provide the prescribing physician with a copy of the:

(1) Qualifications, duties, and responsibilities of agency personnel who deliver the home medical equipment services; and

(2) Instructions given to the client and the client's caregivers.

D. Client Records. The agency shall maintain a client record for each client receiving home medical equipment services in accordance with industry standards, including but not limited to:

(1) Physician order for the provision of home medical equipment services;

(2) Any significant change of condition;

(3) Services provided; and

(4) Any other pertinent information regarding the client being served.

E. An agency shall ensure that the installation, maintenance, repair, and storage of home medical equipment comply with the manufacturer's specifications.

.20 Sanctions.

A. If the Secretary determines that an agency has violated this chapter, the Secretary, in addition to the sanctions set forth in Regulations .21—.27 of this chapter may:

(1) Restrict the number of clients the agency may serve;

(2) Limit the types of clients an agency may serve;

(3) Require the licensee, and any of its staff, to receive remedial instruction in a specific area;

(4) Require the agency to use the services of a management firm that is approved by the Department;

(5) Mandate staffing patterns that specify the number of personnel or personnel qualifications, or both;

(6) Direct the licensee to correct the violations in a specific manner or within a specified timeframe;

(7) Notify, or require the agency to notify, the client, the client representative, or the family of any client who is affected by the noncompliance;

(8) Increase the frequency of monitoring visits during a specified period of time; or

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(9) Establish certain conditions for continued operation, including time limits for continued operation and for compliance.

B. If the Secretary determines that the licensee has violated a condition or requirement of an imposed sanction, the Secretary may suspend or revoke the license.

C. A licensee aggrieved by the imposition of a sanction under §A(1) or (2) or B of this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .28 of this chapter.

.21 Civil Money Penalties.

A. The Secretary may impose a civil money penalty on an agency if a deficiency or continuing pattern of deficiencies exists in the residential service agency.

B. In determining whether a civil money penalty will be imposed, the Secretary shall consider the following factors:

(1) Nature, number, and seriousness of the deficiencies;

(2) The extent to which the deficiency or deficiencies are part of a continuing pattern during the preceding 24 months;

(3) The degree of risk to the health, life, or safety of the clients of the agency that is caused by the deficiency or deficiencies;

(4) The efforts made by, and the ability of, the agency to correct the deficiency or deficiencies; and

(5) An agency's prior history of compliance.

C. If the Department determines that a deficiency or a continuing pattern of deficiencies exists, the Department shall notify the agency of the deficiency or deficiencies and may:

(1) Permit the agency the opportunity to correct the deficiencies by a specified date;

(2) Impose a civil money penalty of up to \$1,000 per day until sustained compliance is achieved; or

(3) Impose a civil money penalty for each instance of violation.

D. If the Department permits an agency the opportunity to correct the deficiencies by a specific date, and the agency fails to comply with this requirement, the Department may impose a civil penalty of up to \$1,000 for each day of violation until correction of the

deficiency or deficiencies has been verified and sustained compliance has been maintained.

E. If the Department proposes to impose a civil money penalty, the Secretary shall issue an order which shall state the:

- (1) Deficiency or deficiencies on which the order is based;
- (2) Amount of the civil money penalties to be imposed;
- (3) Manner in which the amount of the civil money penalty was calculated; and
- (4) Appeal rights.

.22 Amount of Civil Money Penalties.

A. A civil money penalty imposed on a person under this chapter may not exceed \$10,000 per instance or, as provided in Regulation .21 of this chapter, \$1,000 per day.

B. In setting the amount of the civil money penalty under this chapter, the Secretary shall consider the following factors:

- (1) Nature, number, and seriousness of the deficiencies;
- (2) The degree of risk to the health, life, or safety of the clients of the agency that is caused by the deficiency or deficiencies;
- (3) The efforts made by, and ability of, the agency to correct the deficiency or deficiencies;
- (4) Whether the amount of the civil money penalty will jeopardize the financial ability of the agency to continue operation as an agency;
- (5) Prior history of compliance by the agency; and
- (6) Other factors as justice may require.

C. A person aggrieved by the action of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .28 of this chapter.

.23 Civil Money Penalties — Hearings.

A. A hearing on the appeal shall be held consistent with State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland.

B. The Secretary shall have the burden of proof with respect to the imposition of the civil money penalties under this chapter.

.24 Emergency Suspension.

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

A. The Secretary may immediately suspend a license on finding that the public health, safety, or welfare imperatively requires emergency action

B. The Department shall deliver a written notice to the licensee:

(1) Informing the licensee of the emergency suspension;

(2) Giving the reasons for the action, and the regulation or regulations with which the licensee has failed to comply that forms the basis for the emergency suspension; and

(3) Notifying the licensee of its right to request a hearing and to be represented by counsel.

C. The filing of a hearing request does not stay the emergency action.

D. When a license is suspended by emergency action:

(1) The agency shall immediately return the license to the Department;

(2) The agency shall immediately stop providing services; and

(3) The agency shall notify competent clients and client representatives about the suspension and make every reasonable effort to assist them in making other arrangements for services.

E. A person aggrieved by the action of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .28 of this chapter.

F. Show Cause Hearing.

(1) In addition to the right to request an evidentiary hearing in accordance with Regulation .28 of this chapter, a person aggrieved by the action of the Secretary under this regulation shall be provided with the opportunity for a hearing to show cause why the Department should lift the summary suspension before the evidentiary hearing.

(2) The show cause hearing shall be held promptly.

(3) The show cause hearing shall be a nonevidentiary hearing to provide the parties with an opportunity for oral argument on the summary suspension.

(4) The show cause hearing shall be conducted before the Secretary, or a designee of the Secretary, who:

(a) Shall determine procedural issues;

(b) May impose reasonable time limits on each party's oral argument; and

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

(c) Shall make rulings reasonably necessary to facilitate the effective and efficient operation of the show cause hearing.

(5) At the conclusion of the show cause hearing, the Secretary or the Secretary's designee may:

(a) Affirm the order of summary suspension;

(b) Rescind the order of summary suspension;

(c) Enter into a consent order; or

(d) Enter into an interim order warranted by the circumstances of the case, including one providing for a stay of the summary suspension subject to certain conditions.

(6) After the show cause hearing, if the Secretary or the Secretary's designee decides to continue the summary suspension, the person aggrieved by the decision may request an evidentiary hearing before the Office of Administrative Hearings in accordance with Regulation .28 of this chapter.

G. If the Secretary's final decision does not uphold the emergency suspension, the agency may resume operation.

.25 Denial or Revocation of a License.

The Secretary, for cause shown, may deny, revoke, or refuse to reissue any license issued for inability or failure to comply with the regulations of this chapter. This action is subject to the provisions of the Administrative Procedure Act, State Government Article, §10-201 et seq., Annotated Code of Maryland.

.26 Notice to Clients.

Unless otherwise ordered by the Secretary, the agency shall notify each competent client and each client representative within at least 30 days of:

A. Any significant change of licensure status;

B. A voluntary surrender of its agency license; or

C. Denial, revocation, or suspension of the license.

.27 Penalty for Unlicensed Operation.

A person that operates a residential service agency without a license may be assessed a civil money penalty by the Department not to exceed \$10,000 per violation and, additionally, is guilty of a misdemeanor and, on conviction, is subject to a criminal fine

COMAR 10.07.05 Residential Service Agencies
EFFECTIVE: MAY 1, 2012

not exceeding \$1,000 for the first offense and \$10,000 for each subsequent offense. Each day that a violation is continued after the first conviction is a separate offense.

.28 Hearings.

A. An agency shall file a request for a hearing with the Office of Administrative Hearings, with a copy to the Office of Health Care Quality, not later than 30 days after receipt of notice of the Secretary's action. The request shall include a copy of the Secretary's action.

B. A hearing requested under this chapter shall be conducted in accordance with State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland, and COMAR 10.01.03 and 28.02.01.

C. The burden of proof is as provided in COMAR 10.01.03.28.

D. Unless otherwise stated in this chapter, the Office of Administrative Hearings shall issue a proposed decision within the time frames set forth in State Government Article, §10-205, Annotated Code of Maryland.

E. An aggrieved party may file exceptions as provided in COMAR 10.01.03.35.

F. A final decision by the Secretary shall be issued in accordance with COMAR 10.01.03.35.

Administrative History

Effective date: January 17, 1994 (21:1 Md. R. 33)

Regulation .01B amended effective June 2, 1997 (24:11 Md. R. 793)

Regulation .02 amended effective June 2, 1997 (24:11 Md. R. 793)

Regulation .03C repealed effective June 2, 1997 (24:11 Md. R. 793)

Regulation .05-1 adopted effective June 2, 1997 (24:11 Md. R. 793)

Chapter revised effective May 1, 2012 (38:21 Md.R. 1277-1278)